Notice of Allowability	Application No.	Applicant(s)	
	09/855,342	CALIGIURI ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *30 July 2007*.

2. ☒ The allowed claim(s) is/are *74 and 79-87*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20070807* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Susan Abrahamsom, Ph.D. on August 7, 2007.

3. The application has been amended as follows:

In the claims:

The following set of claims has replaced the set of claims submitted as part of the amendment filed July 30, 2007:

Claims 1-73. (Cancelled)

Claim 74. (Previously Presented) A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with the recombinant, humanized anti-HER2 antibody Trastuzumab and the recombinant des-alanyl-1, serine-125 human interleukin-2 molecule Aldesleukin, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said Aldesleukin in combination with a dosing regimen for said Trastuzumab, wherein said dosing regimen for said Trastuzumab comprises administering to said subject at least one therapeutically effective dose of said Trastuzumab, wherein said therapeutically effective dose of said Trastuzumab is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically

effective dose of said Aldesleukin is in the range from about 0.5 MIU/m2 to about 4.0 MIU/m2.

Claims 75-78. (Cancelled)

Claim 79. (Currently Amended) A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with the recombinant, humanized anti-HER2 antibody Trastuzumab and [[an]] a native human IL-2 polypeptide, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 polypeptide in combination with a dosing regimen for said Trastuzumab, wherein said dosing regimen for said ~~humanized anti-HER2 antibody~~ Trastuzumab comprises administering to said subject at least one therapeutically effective dose of said Trastuzumab, wherein said therapeutically effective dose of said Trastuzumab is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is in the range from about 0.5 MIU/m2 to about 4.0 MIU/m2.

Claim 80. (Previously Presented) The method of claim 74, wherein said therapeutically effective dose of said Aldesleukin is administered as a pharmaceutical composition selected from the group consisting of a monomeric Aldesleukin pharmaceutical composition, a multimeric Aldesleukin pharmaceutical composition, a lyophilized Aldesleukin pharmaceutical composition, and a spray-dried Aldesleukin pharmaceutical composition.

Claim 81. (Previously Presented) The method of claim 74, wherein said therapeutically effective dose of said Trastuzumab is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said Aldesleukin is in the range from about 0.6 MIU/m2 to about 3.0 MIU/m2.

Claim 82. (Previously Presented) The method of claim 81, wherein said therapeutically effective dose of said Trastuzumab is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said Aldesleukin is in the range from about 0.8 MIU/m2 to about 1.5 MIU/m2.

Claim 83. (Previously Presented) The method of claim 82, wherein said therapeutically effective dose of said Trastuzumab is about 4.0 mg/kg and wherein said therapeutically effective dose of said Aldesleukin is about 1.0 MIU/m2.

Claim 84. (Currently Amended) The method of claim 79, wherein said therapeutically effective dose of said IL-2 polypeptide is administered as a pharmaceutical composition selected from the group consisting of a monomeric IL-2 pharmaceutical composition, a multimeric IL-2 pharmaceutical composition, a lyophilized IL-2 pharmaceutical composition, and a spray-dried IL-2 pharmaceutical composition.

Claim 85. (Previously Presented) The method of claim 79, wherein said therapeutically effective dose of said ~~anti-HER2 antibody~~ Trastuzumab is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is in the range from about 0.6 MIU/m2 to about 3.0 MIU/m2.

Claim 86. (Previously Presented) The method of claim 85, wherein said therapeutically effective dose of said ~~anti-HER2 antibody~~ Trastuzumab is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL2 polypeptide is in the range from about 0.8 MIU/m2 to about 1.5 MIU/m2.

Claim 87. (Previously Presented) The method of claim 86, wherein said therapeutically effective dose of said ~~anti-HER2 antibody~~ Trastuzumab is about 4.0

mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is about 1.0 MIU/m2.

Conclusion

4. Claims 74 and 79-87 have been allowed.

5. Claims 74 and 79-87 have been renumbered as claims 1, 6, 2-5, and 7-10, respectively.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
August 7, 2007